IN THE SPECIFICATION:

Please replace paragraph number **[0002]** with the following rewritten paragraph:

**[0002]** Two random people have approximately 99.9% identical genetic material. That 0.1% difference not only distinguishes ~~us~~ individual people from one another, but can serve as a basis for excluding individuals from insurance, employment, adoption, education, and numerous other life events. For example, a federal study of genetic discrimination based on genotype included treated hereditary hemochromatosis (HH) as one of only five genotypes possibly providing a basis for discrimination. HH was selected because if diagnosed early and properly managed, the affected individual has no greater morbidity or mortality risk than a member of the general population. Therefore, the sole source of discrimination would be based on genotype, not phenotype. Since the publication of ~~those~~ these results, state and federal legislatures have, to varying degrees, attempted to legislate protection from such discrimination. Similar reports have indicated potential consequences, including loss of medical ~~insurance~~ insurance, that can be suffered, if a subject tests positive for a particular disease or genetic pre-disposition. Beyond the negative effects that can be suffered by the patient or subject, longer term negative effects, such as the use of family history information in setting insurance premiums, may adversely affect a potential patient's children and thereby discourage the patient from having a test performed (Human Genetics Commission (2001), Comments to inform the Government response to the House of Commons report on Genetics and Insurance, HC 174).

Please replace paragraph number **[0007]** with the following rewritten paragraph:

**[0007]** The lack of testing may have serious repercussions for both the patient and society in general. Late diagnosis of serious health issues may decrease treatment options and increased cost for those treatments. For example, a test showing a predisposition to breast cancer (*e.g.*, BRAC1 or BRAC2 tests) may lead to increased screening and an earlier diagnosis. An earlier diagnosis increases the chance that cancer can ultimately be treated and may reduce the cost of treatment. However, a positive test result for a mutation in ~~BRAC 1~~ BRAC1 or ~~BRAC 2~~

BRAC2 does not indicate the presence of breast cancer or indicate that breast cancer will develop. Thus, a woman and her female offspring have to face the risk of losing health care coverage, being fired or other negative effects, simply to detect an increase in the woman's probability of developing the disease.

Please replace paragraph number **[0013]** with the following rewritten paragraph:

**[0013]** Another aspect of the invention relates to a method wherein the biological sample is obtained at the testing facility and the testing facility uses the unique numerical identifier to identify the patient. In addition, the request from the patient may be conducted through an internet site and/or the test results~~are~~ may be provided to the patient through an internet site.

Please replace paragraph number **[0015]** with the following rewritten paragraph:

**[0015]** Another aspect of the invention relates to determining if the patient has a positive test result for a human malady or predisposition to a human malady, and providing or making available information regarding the human malady or the predisposition to a human malady to the patient prior to providing the test result. In addition, the invention relates to querying the patient to determine if the patient desires~~counseling;~~ counseling, and providing the patient with counseling, wherein the counselor provides the test results. Alternatively, the invention relates to querying the patient regarding desired online counseling; and providing an instant messaging account number and instructions for using the instant messaging account, wherein the patient has indicated a desire for online counseling, and connecting a counselor by the instant messaging account to the patient, thereby providing additional information to the patient.

Please replace paragraph number **[0022]** with the following rewritten paragraph:

**[0022]** Representative tests that may be used in relation to the current system and methods include, but are not limited to, Alzheimers, Osteoporosis, Drug Use, DNA Genetics, Infertility, Paternity,~~HIV/Aids~~ HIV/AIDS, Hepatitis, Body Fat Scales, Breathalyzers, CardioChek, Cholesterol, Diabetes, Sexually Transmitted Diseases (STDs), Carpal Tunnel and Cancers, such as, Breast, Prostate, Colon and Skin cancer. The test may be based on saliva, hair, blood, urine, stool, or other biological samples or fluids. These tests may utilize assays that include, but are not limited to, Enzyme Linked Immunosorbent Assay (ELISA), Western Blot tests, hybridization, PCR, GC/MS, TLC and other nucleic acid and protein based tests.

Please replace paragraph number **[0023]** with the following rewritten paragraph:

**[0023]** Various genetic tests can be used with the present invention. These include, but are not limited to, tests for breast cancer, Haemophilia, Duchenne's muscular dystrophy, Becker's muscular dystrophy, Adrenoleukodystrophy, Beta thalassemia, Cystic Fibrosis, Fragile X, Familial Adenomatous Polyposis (FAP), Huntington's disease, Hurler syndrome, Neurofibromatosis, Phenylketonuria, Long QT syndrome, Lesch Nyhan syndrome, Spinal Muscular Atrophy, Von Hippel Lindau, hearing impairment (for example, the GJB2 gene) and Tuberous sclerosis. For a more complete list of heritable human maladies, see Candidate Genes to Inherited Diseases, available at http://www.bork.embl-heidelberg.de/g2d, the contents of which are incorporated~~hereto~~ herein by reference.

Please replace paragraph number **[0024]** with the following rewritten paragraph:

**[0024]** Any HIV, sexually transmitted disease (STD), or genetic testing system should have at least one mechanism to maintain the anonymity of the patient. In addition, the system may also include at least one mechanism to monitor: (i) if the test results have been viewed; and (ii) if the subject requires counseling and/or has received counseling. The testing system must be able to deliver confidential test results (and, optionally, counseling) to numerous subjects without the loss of the patients anonymity. Test results may be delivered over the~~internet~~ Internet, over the telephone, or in person. However, in each case, the subject's identity is maintained in confidence through the use of a unique personal numerical identifier.

Please replace paragraph number **[0025]** with the following rewritten paragraph:

**[0025]** The invention maintains the anonymity of the patient by separating the patient's personal information from the testing procedure. Thus, the testing is conducted in an environment where the patient is identified solely by a unique personal numerical identifier, such as a PIN. For example, the patient contacts an identification generation center that can record any necessary personal information, takes payment for the tests to be conducted, provides the patient with the necessary information regarding where and how to conduct the test, where and how to retrieve the results, and assigns the patient a personal identification number. The patient then conducts the test at home and mails the sample to an appropriate testing facility or has the sample drawn at a testing facility. However, in either case, the patient is identified at the testing facility solely by his or her PIN and not by personal information. Thus, if the patient has the sample drawn at the testing facility, the patient is admitted to the facility, where appropriate, and the sample is drawn under the patient's PIN number. As a part of maintaining the anonymity of the patient, payment for the test to be performed is, likewise, submitted to the testing facility by reference to the PIN. Thus, any personal information, such as that associated with a credit card or personal check, is not associated with the generation of the PIN and ~~are~~ is separated from the test results. For example, transmittal of the medical test to be conducted and payment for performing and reporting the test may be transmitted by the identification-generation center (IGC) to the testing facility. Thus, the testing facility receives payment for specified tests and a PIN assigned to those tests, without compromising the ~~patients~~ patient's identity. In particular, the IGC does not receive the test results. The patient's personal information, such as name or address, is thereby disconnected from the test results. Thus, test results are connected only to the PIN and are not ~~be~~ linked to the patient's personal information.

Please replace paragraph number **[0027]** with the following rewritten paragraph:

**[0027]** In a particular embodiment, the invention provides a method of separating the patient's personal information from the test results. Specifically, the identification generation center (IGC), which has access to the patient's personal information and PIN, is separated from the testing facility, which has access to the test results and PIN. However, the IGC and testing facility are prevented from accessing information particular ~~information from~~ to the other. Thus, the IGC does not have access to test results and the testing facility does not have access to personal information that could compromise the patient's anonymity. The invention thereby reduces the risk or prevents release of the patient's identity, for example, through mistaken or accidental release.

Please replace paragraph number **[0028]** with the following rewritten paragraph:

**[0028]** Test results may be released to the holder of the appropriate PIN through an anonymous telephone system, the ~~internet~~ internet (*e.g.*, a secure web site), or in person. For example, a telephone system may be established to handle incoming telephone calls initiated by anonymous callers, each of the anonymous callers having previously provided a specimen for evaluation to a testing facility. In this example, a telephone call initiated by an anonymous caller is received by a call routing and handling system. The anonymous caller is prompted by the call routing and handling system to transmit a personal identification number (PIN) corresponding to a specimen previously provided to the testing facility by the anonymous caller. Next, the PIN transmitted by the anonymous caller is received by the call routing and handling system, and test result information is retrieved through access from a previously-received PIN submission and verification. A call handler for processing the telephone call may be selected in response to the test result information. The selected call handler may be chosen from a plurality of candidate call handlers. The telephone call is then routed to the selected call handler and test result information corresponding to the PIN is provided to the anonymous caller by the selected call handler.

Please replace paragraph number **[0029]** with the following rewritten paragraph:

**[0029]** The test may include a kit having all the necessary elements for the person taking the test to be able to obtain a test specimen in private and information regarding submission of the specimen in connection with the PIN. The test results and PIN may be linked by creating or activating a personal electronic file through a software program in a computer system that can be both created and subsequently accessed anonymously and remotely from a telephone or through the internet. The electronic file ~~that is~~ set up is ~~identified~~ identifiable only by the PIN. Because the file connecting the results to the PIN is created at a testing facility separate from the IGC, the identity of the person taking the test is unknown to others, thus, protecting the anonymity of the person taking the test.

Please replace paragraph number **[0030]** with the following rewritten paragraph:

**[0030]** In a particular embodiment, pre-test counseling regarding the test and the test results may optionally be offered by the identification generation center setting up the PIN. The pre-test counseling is an opportunity for the person taking the test to seek assistance in the form of counseling to cope with the possible results that could result if the testing reveals a positive result. Pre-test counseling may provide the patient with information regarding the appropriate tests for a particular situation and the nature of those tests. For example, the patient may seek information regarding the possibility of transmitting a medical condition, or a predisposition to a medical condition, to the patient's offspring or of developing a medical condition in the future. Pre-test counseling is counseling done prior to a test result. Therefore, a patient is unlikely to require the anonymity of the invention at that time. However, once the patient determines the appropriate test to take and receives counseling regarding the nature of the test and the consequences of a positive, ~~negative~~ negative, or non-determinative result, the patient may desire to obtain the test results without disclosing their identity. Thus, the patient may seek to use the invention to preserve their identity.

Please replace paragraph number **[0033]** with the following rewritten paragraph:

**[0033]** The test specimen is often a blood sample but can also be another body fluid or tissue like saliva, urine, feces, hair follicles or skin cells. The test specimen is then submitted for analysis at the testing facility. The test specimen is associated with the unique personal identification number to identify and preserve the anonymity of the person taking the test. If the test specimen is to be mailed to the testing facility, the sample is preferably mailed in a pre-addressed envelop without the ~~senders~~ sender's return address.

Please replace paragraph number **[0039]** with the following rewritten paragraph:

**[0039]** When the body fluid to be tested is blood, the kit may include all suitable equipment for blood extraction, including, for example, needles, collection containers (*e.g.*, tubes), alcohol swabs, sterile gauzes, lancets for puncturing the skin. Such a test kit may further include at least one bandage to protect the puncture site after the blood sample is produced. The test kit (as well as other test kits described herein) may further include an appropriate mailing container, wherein the mailing container is preferably pre-addressed. The blood sample is acquired by placing collected blood on a blood specimen collection ~~devise~~ device provided in the kit. Preferably, sufficient sample is provided to conduct the test at least twice, and more preferably, sufficient sample is provided to allow for multiple tests.

Please replace paragraph number **[0041]** with the following rewritten paragraph:

**[0041]** When the sample to be analyzed or tested is a nucleic acid based test, the specimen may be blood, a mucosal swab, hair folicals or skin cells. Depending on the assay to be ~~conducted~~ conducted, more or less nucleic acid may be required and the sample container will be appropriately sized, depending on the source from which nucleic acid is to be obtained and whether amplification is possible. Where a mucosal swab is appropriate and desired, the test kit will preferably include an appropriate swab, preferably separately packaged to be unsealed immediately prior to use, and a sample contained suitable to hold the swab and maintain the sample is a satisfactory condition. The mucosal swab may be obtained by inserting a swab into the mouth and scraping the side of the check with the swab. Preferably, sufficient sample is provided to conduct the test at least twice, more preferably sufficient sample is provided to allow for additional tests. For example, multiple swabs may be provided and sent to the testing facility. Other samples and collection ~~devises~~ devices are known in the art and may be used to collect and transmit the appropriate sample.

Please replace paragraph number **[0042]** with the following rewritten paragraph:

**[0042]** Preferably, a testing facility should receive a sufficient quantity of a sample to perform the desired test at least twice, thereby allowing for verification of the test accuracy. The invention also provides for a testing facility to receive sufficient sample to perform additional tests, thus, the testing facility may maintain the sample and identify the same in relation with the PIN. The patient may then ~~contact,~~ contact the IGC or the testing facility to order additional tests to be performed on the sample. Preferably, where additional payments for supplemental tests are required, the patient can make those payments to the IGC in order to preserve patient anonymity. The IGC would then forward a suitable payment to the testing facility.

Please replace paragraph number **[0043]** with the following rewritten paragraph:

**[0043]** Referring now to FIG. 1, there is shown a flow diagram illustrating the general operation of a system for delivering confidential medical test results to patients in accordance with an embodiment of the invention. The IGC 10 receives a patient request and obtains any necessary personal information and payment from the patient. At this time, the IGC may also provide counseling to the patient where appropriate and if necessary. The information generation center generates a PIN 12, which is preferably a randomly generated and unique identifier. The PIN may include numbers, alphabetical characters and/or other symbols, so long as the PIN does not provide information regarding the patient's identity. The PIN may include one or more separate character strings, such as a password and a user ID, where appropriate. The PIN may be provided in bar code where appropriate and desirable, for example, on a sample container. The PIN and payment are transmitted 13 to an appropriate testing facility. The testing facility merely receives the payment and PIN 14. The testing facility may, where necessary, communicate with the IGC to clarify or acknowledge receipt of payment and the corresponding PIN. It is understood that the IGC will not divulge any information that could lead to the identification of a patient by the testing facility. Subsequently, a biological sample is transmitted to the testing facility 9, which performs the ordered tests 15 and associates the results with the PIN 16.

Following the association between the PIN and the results, the patient is provided a method of accessing the results, which can be accessed with the proper PIN 17. If desired, the patient may then instruct the testing facility to delete a portion or all of the recorded results 18. The patient may optionally delete a portion or all of the posted results at a later date.

Please replace paragraph number **[0044]** with the following rewritten paragraph:

**[0044]** Referring now to FIG. 2, there is shown a flow diagram illustrating the general operation of the IGC 10. A patient desiring to have a test performed, but wishing to maintain their anonymity, contacts an IGC 20. The IGC will take that personal information 11 necessary to determine or identify the appropriate tests to be conducted. The IGC may store the personal information~~ 21~~, the nature of the tests to be administered and the payment 21. The patient and IGC then determine the appropriate tests to be performed 22. Alternatively, the IGC may delete the~~ patients~~ patient's personal information and/or PIN after a specified period of time, after completion of a particular event (*e.g.*, completion of the testing), or other predetermined period of time.

Please replace paragraph number **[0045]** with the following rewritten paragraph:

**[0045]** Many of the patients that will benefit most from a system of anonymity are seeking tests that may reveal the presence of terminal illness or serious medical consequences. As a result, the IGC can determine if pre-test counseling is necessary 23. Therefore,~~ pre-testing~~ pre-test counseling 24, may be provided by the IGC or the IGC may refer the patient to other sources of counseling. The pre-test counseling can provide an opportunity to assist the patient to cope with the possibility of an adverse test result, referred to herein as a positive result, or gather more information on a particular condition. ~~Pre-testing~~Pre-test counseling may also assist the patient in determining what tests should be conducted, the risks and benefits of such tests, and/or the nature of the test (*i.e.*, what a predisposition to cancer means to the patient and how to use the information). Pre-test counseling may affect the~~ patients~~ patient's ultimate decision to have the test performed or may affect the choice of the appropriate test, which may benefit from follow-up counseling. Once the appropriate test(s) are determined 22 and all desired or appropriate pre-test counseling 24 is completed, an appropriate testing facility is selected 25 based on the nature of the tests to be performed. Having determined the desired tests and the testing facility to be ~~used~~ used, appropriate fees are calculated 26, which includes the fees to be charged by the testing facility ~~14~~. Fees for the services provided by the IGC, ~~counselors~~ counselors, and/or other services may be included in the fee calculation. The appropriate fees are then paid to the IGC 26. Once the fees are collected or accounted for, the IGC generates a PIN 12. Preferably, the total fees paid are deposited into an account managed by the IGC, which then reissues the fees necessary to pay the testing facility 13. Thus, protecting the identification of the patient that would result from the patient paying fees to the testing facility in any form other than cash. Thus, in this ~~embodiment~~ embodiment, generation of a PIN, which may be performed by a computer that generates a unique random number or character set, automatically connects the payment order to the newly generated PIN 28. The IGC then transmits the ~~PIN~~ PIN, and any required ~~payment~~ payment, to the testing facility for completion of the desired testing and ~~to set~~ sets up an account or database from which the patient may access the test results once the PIN is verified.

Please replace paragraph number [0046] with the following rewritten paragraph:

[0046] Referring now to FIG. 3, there is shown a flow diagram illustrating the general operation of the testing facility according to a particular embodiment of the invention. The testing facility receives a sample with a PIN and payment for testing 14. The PIN transmitted by the IGC indicates the tests to be performed on the sample. The testing facility then performs the requested tests ~~14~~ 15. The tests performed by the testing facility may be any test, for example, the patient may be tested for mutations in breast cancer genes, colon cancer (FAP) ~~genes~~ genes, and HIV infection. Once the tests are performed 15, the test results are associated with or connected to a file or database identified by the patient's PIN 16. Since the invention relates to diseases or predispositions generally having serious ramifications for the patient, one particular embodiment includes identifying positive results 34 (*i.e.*, those results that indicate the presence of a disease state in the patient, indicate a predisposition to a disease state, or the presence of a heritable trait that may be passed to the patient's offspring) and selecting appropriate information 36 to be provided to the patient. The information should correlate with the nature of the test performed, which can effect the information that is appropriate to the results. Furthermore, where desirable and appropriate, a determination may be made as to whether or not to provide counseling to the patient 37. Such counseling may be in addition to any ~~pre-testing~~ pre-test counseling provided by the IGC. The test results are then provided to the patient 17 or 17′, the patient can then be directed to a form of counseling 38.

Please replace paragraph number **[0047]** with the following rewritten paragraph:

**[0047]** Providing the results to the patient 17 or 17′ requires that the patient present the appropriate PIN and, optionally, other information, wherein the other information does not compromise their identity. For example, the patient may access the information through a web site by entering the PIN 30 and other information (such as, a "User name," which may alternatively be provided by the IGC as a part of the PIN, access codes identifying the nature of the tests performed, the date the PIN was ~~established~~ established, or the like). The PIN and other information is then verified 31 by checking the entry against a database having the assigned PINs therein. If the entry does not satisfy the verification requirements the patient may be asked to re-enter the appropriate information. The system may be designed to terminate contact (or disallow access to results) if an incorrect entry is made more than a specified number of times. Upon entry of the correct PIN and other information, the test results 17 or 17′ are shown to the patient. The patient may be prompted with a question asking if the patient would like to delete the record of the results 18. The prompt may allow the patient to delete all of the information or selected aspects of the information.

Please replace paragraph number **[0048]** with the following rewritten paragraph:

**[0048]** Alternatively, the patient may be provided the results through a telephone system. The telephone system also requires ~~that the patient~~ patient to present the appropriate PIN and other information, wherein the other information does not compromise the patient's identity. In this embodiment, the patient may access the information by entering the PIN and, optionally, other information (such as, access codes identifying the nature of the tests performed, the date the PIN was ~~established~~ established, or the like) using the telephone touch-tone buttons. The PIN and other information is verified by checking the entered information against at least one database or reference source having at least the currently assigned PINs therein. If the entry does not satisfy the verification requirements the patient may be asked to re-enter the appropriate information 32. The system may be designed to terminate contact (or disallow access to results) if an incorrect entry is made more than a specified number of times 33, for example, incorrect entry of the PIN three consecutive times may indicate an inappropriate attempt to access information and the call may be terminated. Upon entry of the correct PIN and other information, the test results 17 or 17′ are reported to the patient. The patient may be prompted with a question asking if the patient would like to delete the record of the results 18. The prompt may allow the patient to delete all of the information or selected aspects of the information.

Please replace paragraph number **[0050]** with the following rewritten paragraph:

**[0050]** The test results may be screened for those results that are positive for a disease or predisposition of a disease 34. The positive results may then be correlated with the test performed and/or the malady represented by the test ~~35~~ and appropriate information correlated with the tests/malady 36. Optionally, a determination may be made regarding the necessity or desirability of providing counseling to the patient 37. A determination that counseling should be provided can trigger the system to provide the appropriate information. For example, the patient may be provided a form of counseling, wherein information is relayed over the phone, either by an automated voice or by a counselor 38 that is provided via telephone to the patient. The patient then receives the test results and information 17. If the patient tests negative for a human malady or predisposition for a malady, the patient may be provided the test results directly 17′.

Please replace paragraph number **[0051]** with the following rewritten paragraph:

**[0051]** Tests that may be used in conjunction with the invention are known in the art and include, but are not limited to those described in U.S. Patents: 6,465,629; 6,448,041; 6,440,699; 6,423,491; 6,417,342; 6,416,961; 6,372,896; 6,342,581; 6,333,403; 6,316,204; 6,312,909; 6,307,019; 6,218,146; 6,180,776; 6,162,897; 6,090,578; 6,599,719; and 6,599,716, the contents of each of which are incorporated by reference herein. Methods of testing that may be used in conjunction with the invention are known in the art and include, but are not limited to those described in U.S. Patents: 6,458,536; 6,365,350; 6,340,566; 6,297,051; 6,297,041; and 6,599,700; the contents of which are incorporated by reference herein.

Please replace paragraph number **[0055]** with the following rewritten paragraph:

**[0055]** In another embodiment, the testing facility, upon receipt of the PIN from the IGC, will generate and store the PIN, the tests to be performed, and the estimated time for completion of the tests in a status database. The testing laboratory may then indicate a delay or the completion of one or more tests, which will be used to update the status database. The estimated date of completing the testing may be used to provide the patient with information regarding the availability of the test results. For example, the patient may log onto the web site to access the test results and, after entry of the appropriate PIN and other information, be informed that the test results are not currently available, but may be available following a specified date and/or time.

Please replace paragraph number **[0059]** with the following rewritten paragraph:

**[0059]** In accordance with a another embodiment, an automated web page and routing system facilitates the providing of the test result and counseling information to the patient either via a prepared web page or a series of prepared messages which may be displayed on one or more web pages. Alternatively, the web page may direct the patient to a counselor and/or customer service representatives. Previously prepared messages ~~are~~ may be used by the web site and routing system for informing a patient of test results. Alternatively, in the case of patients that test positive or screen positive for ~~the~~ a malady or predisposition (*e.g.*, HIV virus), or whose test results are inconclusive, the web site and routing system may transfer the patient to live counselors who then inform the patient of their test results. In cases where the test results for the patient are not yet available because the testing laboratory has not completed the test associated with the patient's PIN, the web site may transfer the patient to a recorded message for the patient indicating the date that the patient should log back in to obtain the test results. Alternatively, the patient may be directed to a web page having prepared information relevant to the malady, predisposition, and/or the nature of the test result. For example, the patient may be directed to a comprehensive database of referral organization information including, the names, addresses and phone numbers of individuals and organizations that can provide additional information or counseling relating to the malady or predisposition, such as those provided by the U.S. Centers for Disease Control.